



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,380	02/08/2002	Li-Lan H. Chen	366325-503	1761

25561 7590 03/06/2006

JOHN W. RYAN
C/O DECHERT LLP
PRINCETON PIKE CORPORATION CENTER
P.O. BOX 5218
PRINCETON, NJ 08543-5218

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/071,380		CHEN ET AL.	
	Examiner		Art Unit	
	Hasan S. Ahmed		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 and 17-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicants' response filed on 29 November 2005 is acknowledged.

Claims 6-9 and 17-44 remain withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 10-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zyck, et. al., US 6,541,048 B2 ("048") for the reasons set forth in the prior office action mailed on 29 October 2004.

Although the '048 reference is silent as to the composition being substantially free of uncomplexed active agent, it adds the same ingredient (glycyrrhizin) as Applicants for the same property (flavoring/sweetening) desired by Applicants. It is obvious to one of ordinary skill in the art that the properties of a compound and the compound itself are inseparable; i.e. use of glycyrrhizin as a flavorant or sweetener.

Since the '048 reference recognizes glycyrrhizin as a sweetener, burden shifts to Applicants to establish some unexpected result with a formulation that is free of an uncomplexed active agent.

The claims do not recite any degree of masking. Thus, the presence of sweetener in the '048 reference renders the instant invention obvious.

Claims 1-5 and 10-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto, et. al., US 5,576,014 A ("014") for the reasons set forth in the prior office action cited above.

Although the '014 reference is silent as to the composition being substantially free of uncomplexed active agent, it adds the same ingredient (glycyrrhizin) as Applicants for the same property (flavoring/sweetening) desired by Applicants. It is obvious to one of ordinary skill in the art that the properties of a compound and the compound itself are inseparable; i.e. use of glycyrrhizin as a flavorant or sweetener.

Since the '014 reference recognizes glycyrrhizin as a sweetener, burden shifts to Applicants to establish some unexpected result with a formulation that is free of an uncomplexed active agent.

The claims do not recite any degree of masking. Thus, the presence of sweetener in the '014 reference renders the instant invention obvious.

Response to Arguments

Applicants' arguments filed 29 November 2005 have been fully considered but they are not persuasive.

Applicants argue that the '048 reference does not teach a composition that is substantially free of uncomplexed active agent.

To reiterate, in response to Applicant's argument, since the '048 reference recognizes glycyrrhizin as a sweetener, burden shifts to Applicants to establish the criticality of a formulation that is free of an uncomplexed active agent.

Applicants argue that the '014 reference does not describe use of glycyrrhizin particularly with famotidine and that the amount of glycyrrhizin to be used is not disclosed.

In response to Applicants' argument, the suggestion by the '014 reference that glycyrrhizin may be used as a sweetener in their formulation, and famotidine may be used as an active ingredient in their formulation suffices to find a *prima facie* case of obviousness that one of ordinary skill in the art would combine the two ingredients in a formulation. Furthermore, absent unexpected results, it would have been obvious to one of ordinary skill in the art, through routine experimentation, to determine the appropriate amount of glycyrrhizin to be used in an intrabuccally dissolving compressed molding, as taught by the '014 reference.

Applicants argue that the '014 reference does not teach a composition that is substantially free of uncomplexed active agent.

Again, in response to Applicant's argument, since the '014 reference recognizes glycyrrhizin as a sweetener, burden shifts to Applicants to establish the criticality of a formulation that is free of an uncomplexed active agent.

Conclusion

Claims 1-5 and 10-16 remain rejected.

Claims 6-9 and 17-44 remain withdrawn from consideration.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600